DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

'336 '99 MAY -7 P3:42

Re: Lotemax™ and Alrex™
Docket No.: 98E-0789

MAY - 5 1999

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,996,335, filed by Nicholas S. Bodor, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Lotemax™ and Alrex™, the human drug product claimed by the patent.

The total length of the regulatory review period for Lotemax™ and Alrex™ is 3,092 days. Of this time, 2,017 days occurred during the testing phase and 1,075 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: September 22, 1989.

   The applicant claims January 2, 1989, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 22, 1989, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: March 31, 1995.

   The applicant claims March 29, 1995, as the date the new drug application (NDA) for Lotemax™ and Alrex™ (NDA 20-583) was initially submitted. However, FDA records indicate that NDA 20-583 was submitted on March 9, 1995.

3. The date the application was approved: March 9, 1998.

   FDA has verified the applicant's claim that NDA 20-583 was approved on March 9, 1998.

98E-0789

WET3 / AN8

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Norman H. Stepno, Esq.
Burns, Doane, Swecker & Mathis LLP
P.O. Box 1404
Alexandria, VA 22313-1404

DATE: MAY - 5 1999

TO: Sabrina Crisp, Regulations Policy and Management Staff, HF-26

From: Brian J. Malkin, Associate Director for Patents and Hearings, HFY-20

RE: Federal Register Notice Information for Lotemax™ and Alrex™
Docket No. 98E-0789, FRDTS# OC99130

Attached is a FR Notice for the human drug product, Lotemax™ and Alrex™. This document has been internally reviewed and cleared by OHA.

Please note that Lotemax™ and Alrex™ are trademarks. Therefore, the superscript "TM" notations will be needed.

Please call me if you have any questions. My number is 827-6620 (Rm. 15-22).

Thank you for your assistance.

«FR_Track_No»

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

7335 '99 MAY -7 P3:42

Memorandum

Date: MAY - 5 1999

From: Brian J. Malkin, Associate Director for Patents and Hearings
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application
for Lotemax™ and Alrex™

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned human drug product under the Docket Number **98E-0789** stating that this particular patent is eligible for regulatory review. The Patent Number is **4,996,335**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.

98E-0789